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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,180	02/13/2002	Robert J. Hariri	009516-0050-999	9742

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,180	HARIRI, ROBERT J.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,10,12-18,54 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10,12-18,54 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12/17/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response and amendment filed December 29, 2003 have been entered. Claims 1, 9, 10, 17, 18, and 54 have been amended. Claims 7, 8, 11, 19-53, and 55-59 have been canceled. Claim 60 is newly submitted. Claims 1-6, 9, 10, 12-18, 54, and 60 are pending in the application and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 12/29/03 response would be addressed to the extent that they apply to current rejection.

Claim Objections

The prior objection of claim 11 now applies to claims 1 and 10 in view of claim amendment. In the response, the applicant argues that persons of skilled in the art use the terms OCT-4 and ABC-p when referring to these particular markers, hence no spelling out of the terms is necessary.

The argument has been considered but found not persuasive with respect to the term "ABC-p". During an interview on 3/9/04, subsequent to the 12/29/03 response, the inventor Dr. Hariri clarifies that "ABC-p" refers to the ABC transporter protein family and provides a reference, *Leonard et al*, Oncologist 2003;8:411-24. As such, a survey of art of record indicates that the surface markers widely used for identifying ABC transporters are MDR, bcrp1, ABCG2, or their gene product P-glycoprotein (p-gp) and BCRP, "ABC-

p" does not appear to be a widely accepted abbreviation for a particular marker, accordingly, the objection stands.

Claim 17 is newly objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The prior rejection of claim 11 has been modified in view of claim amendment.

Claims 1-6, 9, 10, 12-18, 54, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are vague and indefinite because of the claim recitation (1 and 10), "ABC-p+". In the response to the prior rejection, the applicant argues that no person of skill in the art would read ABC-p for other meanings but a marker for embryonic-like stem cells.

The argument is not persuasive because it does not clarify what kind of marker the recited ABC-p refers to. During an interview on 3/9/04, subsequent to the response, the inventor Dr. Hariri clarified that "ABC-p" refers to the ABC transporter protein family. As such, a survey of art of record indicates that the surface markers widely used for

identifying ABC transporters are MDR, bcrp1, ABCG2, or their gene product P-glycoprotein (p-gp) and BCRP (e.g. *Bertolini et al*, Br J Haematol 1994;88:318-24 or *Abbott*, Hematol Oncol 2003;21:115-30 or *Leonard et al*, Oncologist 2003;8:411-24), "ABC-p" does not appear to be a widely accepted marker, and the specification fails to define the marker if it differs from the well known MDR, BCRP and ABCG2, and thus, the metes and bounds of the claims could not be readily determined.

Claim 1 is vague and indefinite because the amended claim 1 recites, "wherein said placenta *produces* embryonic-like stem cells that are OCT-4+ and ABC-p+". Since placenta is just a biological tissue, it is unclear how a placenta produces stem cells, thus, the metes and bounds of the claims are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 10, 12-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Sanders* (US 3,862,002), and as evidenced by *Larsson et al* (Angiogenesis 2002;5:107-10) and *Kurtzberg et al* (New Eng J Med 1996;335:157-66), and the rejection applies to new claim 60.

The amended claim 1 recites, "wherein said placenta produces embryonic-like stem cells that are OCT-4+ and ABC-p+". The amended claim 10 recites, viable

embryonic-like stem cells "are OCT-4+ and ABC-p+". Since the limitation defines the characteristics of the stem cells in the placenta, the cited art of record still anticipates the claimed invention because it teaches an isolated mammalian placenta that has been exsanguinated and perfused under sterile conditions. The new claim 60 is drawn to an isolated placenta that has been perfused for more than 48 hours, this limitation was in the original claim 9, and thus, for the same reason on the record, the rejection applies to new claim 60.

In the 12/29/03 response, the applicant argues that the amended claims have made the rejection moot because Sanders does not teach that the placenta comprises or produces embryonic like stem cells that are OCT-4+ and ABC-p+. The applicant goes on to argue that the Kurtzberg teaches obtaining hematopoietic stem cells from placenta blood, not from the placenta itself.

The arguments have been fully considered but found not persuasive for reasons of record and following. The claims are drawn to an isolated and manipulated placenta, not a stem cell. Accordingly, as long as the placenta taught by *Sanders* is from a mammalian, has been isolated, exsanguinated, and perfused in a sterile medium, it meets claim limitation. This is because "WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT." See MPEP 2112.01 or In re Best, 195 USPQ 430, 433 (CCPA 1997). In this case, the placenta recited in *Sanders* is substantially identical to that of the claims, thus, claimed properties of stem cells contained in the placenta are presumed to be inherent. With respect to *Kurtzberg et al,* the reference evidences the

presence of stem cells in the placenta, thus the methods of obtaining stem cells are irrelevant in determining the patentability of the instantly claimed subject matter. Accordingly, the rejection stands.

Claims 1-5,10, 12-14, 16-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Muhlemann et al* (Placenta 1995;16:367-73).

The amended claim 1 recites, "wherein said placenta produces embryonic-like stem cells that are OCT-4+ and ABC-p+". The amended claim 10 recites, viable embryonic-like stem cells "are OCT-4+ and ABC-p+". Since the limitation defines the characteristics of the stem cells in a placenta, the cited art of record still anticipates the claimed invention because it teaches an isolated mammalian placenta that has been exsanguinated and perfused under sterile conditions.

In the 12/29/03 response, the applicant argues that the amended claims have made the rejection moot because *Muhlemann et al* do not teach that the placenta comprises or produces embryonic like stem cells that are OCT-4+ and ABC-p+. The applicants goes on to argue that *Muhlemann et al* teach a different placenta as instantly claimed because the placenta is heavily infected with cytomegalovirus during the perfusion, and would not be useful for producing stem cells.

The arguments have been fully considered but found not persuasive for reasons of record and following. Although the experimental group of placenta in *Muhlemann et al* were exposed with CMV in the 9.5 hrs of experimental perfusion, the experimental placenta during the first two hours of the control period and the control placenta during

the 9.5 hrs experimental period meet the claim limitation. As to the surface markers of the stem cells, the claims are drawn to an isolated and manipulated placenta, not a stem cell. Accordingly, as long as the placenta taught by *Muhlemann et al* is from a mammalian, has been isolated, exsanguinated, and perfused in a sterile medium, it meets claim limitation. "WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT." See MPEP 2112.01 or In re Best, 195 USPQ 430, 433 (CCPA 1997). Accordingly, the rejection stands.

Claim 54 stands rejected under 35 U.S.C. 102(b) as being anticipated by *Ordi et al* (Am J Surg Pathol 1998;8:1006-11).

Amended claim 54 is drawn to an isolated placenta engrafted with a cell, which is neither fetal nor maternal in origin. In the 12/29/03 response, the applicant argues that the amended claim recites "engrafted" to emphasis that the cell is placed into the placenta deliberately as opposed to an infective process.

In response, it appears that the applicant is arguing the claimed product differs from the cited art in that the process of making the product, i.e. whether it is an intended grafting or an unintentional grafting (infection). However, applicants are reminded that "[E]VEN THOUGH PRODUCT-BY-PROCESS CLAIMS ARE LIMITED BY AND DEFINED BY THE PROCESS, DETERMINATION OF PATENTABILITY IS BASED ON THE PRODUCT ITSELF. THE PATENTABILITY OF A PRODUCT DOES NOT DEPEND ON ITS METHOD OF PRODUCTION. IF THE PRODUCT IN THE PRODUCT-BY-PROCESS CLAIM IS THE SAME AS OR OBVIOUS FROM A PRODUCT OF THE PRIOR ART, THE CLAIM IS UNPATENTABLE EVEN THOUGH THE PRIOR PRODUCT WAS MADE BY A DIFFERENT PROCESS."

In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, *Ordi et al* disclose isolated human placentas containing malaria parasite cells (abstract), which is neither fetal nor maternal in origin. Since the parasite cells established their growth in the placenta (engrafted with a cell), the structure of the placenta taught by *Ordi et al* meets claim limitation. Moreover, the specification recites that the placenta may be engrafted with cells not placental in origin (Specification, page 7, 3rd paragraph), and it does not particularly designate the term "engraft" to a particular use, nor excluding a parasitic cell. Thus, the rejection stands.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6, 9, and 10 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/074,976.

Applicants request to revisit the issue until a later time when claims in either the present application or cited application are allowed.

Until the issue as set forth on record is resolved, the rejection stands.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is **703-308-0196**.

JANICE LI
PATENT EXAMINER

Q. Janice Li
Patent Examiner
Art Unit 1632

QL
March 15, 2004